

First-in-Human (FIH) Trial Planning Checklist

A Clinical Strategy & Protocol Readiness

- Cross-functional input on protocol draft
- Clarity on scientific rationale, target population, and study endpoints
- Defined dose escalation strategy (if applicable)
- Inclusion/exclusion criteria vetted for feasibility in real-world setting

Site & Patient Strategy

- Initial KOL or advisory board feedback incorporated into protocol/site plan
- Site-level feasibility initiated (targeting key geographies)
- Recruitment assumptions based on actual patient access, not just prevalence
- Backup sites identified in case of underperformance

S Vendor & CRO Oversight

- RFPs issued to fit-for-purpose CROs
- Defined vendor scopes and handoffs (no overlap or gaps)
- Operational governance plan established (including escalation pathways)
- Risk-sharing or performance-based contract terms explored

Regulatory & CMC Coordination

- Regulatory timeline aligned with submission and anticipated feedback windows
- CMC deliverables mapped to first-patient dosing timeline
- Submission strategy accounts for regional differences (FDA vs. others, if global)



Timeline & Milestone Planning

- Integrated timeline includes clinical, regulatory, CMC, and relevant functional areas
- Key milestones with go/no-go decision points clearly defined
- Internal ownership for each milestone established

(*) Internal Readiness & Resourcing

- Budget assumptions validated against real-world FIH benchmarks
- Internal resource plan finalized
- Communication plan for study governance and investor reporting